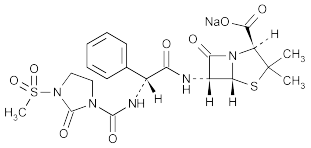
the combined contents of the Capsules, and transfer an accurately weighed portion, equivalent to about 50 mg of mexiletine hydrochloride, to a stoppered, 50-mL centrifuge tube. Add 25.0 mL of *Mobile phase,* insert the stopper, and shake by mechanical means for 15 minutes. Centrifuge, and use the clear supernatant as the *Assay preparation.* [NOTE—Reserve a portion of this solution for use as the *Test solution* in the test for *Chromatographic purity.*]

Procedure—Proceed as directed for *Procedure* in the *Assay* under *Mexiletine Hydrochloride*. Calculate the quantity, in mg, of mexiletine hydrochloride ($C_{11}H_{17}NO \cdot HCl$) in the portion of Capsule contents taken by the formula:

$$25C(r_U / r_S)$$

in which *C* is the concentration, in mg per mL, of USP Mexiletine Hydrochloride RS in the *Standard preparation;* and r_U and r_S are the mexiletine peak responses obtained from the *Assay preparation* and the *Standard preparation,* respectively.

Mezlocillin Sodium



$C_{21}H_{24}NaN_5O_8S_2$ 561.57

4-Thia-1-azabicyclo[3.2.0]heptane-2-carboxylic acid, 3,3-dimethyl-6-[[[[[3-(methylsulfonyl)-2-oxo-1-imidazolidinyl]carbonyl]amino]phenylacetyl]amino]-7-oxo-, monosodium salt, [2*S*-[2α,5α,6β(*S**)]]-.

Sodium (2*S*,5*R*,6*R*)-3,3-dimethyl-6-[(*R*)-2-[3-(methylsulfonyl)-2-oxo-1-imidazolidinecarboxamido]-2-phenylacetamido]-7-oxo-4-thia-1-azabicyclo[3.2.0]heptane-2-carboxylate [59798-30-0].

Monohydrate 579.58

» Mezlocillin Sodium contains the equivalent of not less than 838 µg and not more than 978 µg of mezlocillin ($C_{21}H_{25}N_5O_8S_2$) per mg, calculated on the anhydrous basis.

Packaging and storage—Preserve in tight containers.

Labeling—Where it is intended for use in preparing injectable dosage forms, the label states that it is sterile or must be subjected to further processing during the preparation of injectable dosage forms.

USP Reference standards ⟨11⟩**—**
USP Endotoxin RS
USP Mezlocillin Sodium RS

Identification—

A: Prepare a test solution containing the equivalent of 4 mg of mezlocillin per mL. Prepare a Standard solution of USP Mezlocillin Sodium RS containing 4 mg per mL. Use within 10 minutes after preparation. Apply separately 5 µL of each solution to a thin-layer chromatographic plate coated with a 0.25-mm layer of chromatographic silica gel mixture (see *Chromatography* ⟨621⟩). Place the plate in a suitable chromatographic chamber, and develop the chromatogram with a solvent system consisting of a mixture of methanol, chloroform, water, and pyridine (90:80:30:10) until the solvent front has moved about three-fourths of the length of the plate. Remove the plate from the chamber, and dry with a current of warm air for 10 minutes. Locate the spots on the plate by exposing it to iodine vapors in a closed chamber for about 30 seconds: the R_F value of the principal spot obtained from the test solution corresponds to that obtained from the Standard solution.

B: It responds to the tests for *Sodium* ⟨191⟩.

Specific rotation ⟨781S⟩: between +175° and +195°.

Test solution: 10 mg per mL, in water.

pH ⟨791⟩: between 4.5 and 8.0, in a solution (1 in 10).

Water, *Method I* ⟨921⟩: not more than 6.0%.

Other requirements—Where the label states that Mezlocillin Sodium is sterile, it meets the requirements for *Sterility* and *Bacterial endotoxins* under *Mezlocillin for Injection*. Where the label states that Mezlocillin Sodium must be subjected to further processing during the preparation of injectable dosage forms, it meets the requirements for *Bacterial endotoxins* under *Mezlocillin for Injection*.

Assay—

Mobile phase—Dissolve 4.9 g of monobasic potassium phosphate and 0.54 g of dibasic potassium phosphate in about 500 mL of water, dilute with water to 1000 mL, and mix. Prepare a suitable mixture of this solution and acetonitrile (855:145), and degas. Make adjustments if necessary (see *System Suitability* under *Chromatography* ⟨621⟩).

Standard preparation—Dissolve a suitable quantity of USP Mezlocillin Sodium RS, accurately weighed, in water to obtain a solution having a known concentration of about 500 µg of mezlocillin ($C_{21}H_{25}N_5O_8S_2$) per mL.

Assay preparation—Transfer about 110 mg of Mezlocillin Sodium, accurately weighed, to a 200-mL volumetric flask, dissolve in and dilute with water to volume, and mix.

Chromatographic system (see *Chromatography* ⟨621⟩)—The liquid chromatograph is equipped with a 210-nm detector and a 4-mm × 12.5-cm column containing 5-µm packing L1, and is maintained at 40 ± 1°. The flow rate is about 2 mL per minute. Chromatograph the *Standard preparation*, and record the responses as directed under *Procedure:* the column efficiency is not less than 1500 theoretical plates, the tailing factor is not more than 1.5, and the relative standard deviation for replicate injections is not more than 1.5%.

Procedure—[NOTE—Use peak areas where peak responses are indicated.] Separately inject equal volumes (about 20 µL) of the *Standard preparation* and the *Assay preparation* into the chromatograph, record the chromatograms, and measure the responses for the major peaks. Calculate the quantity, in µg per mg, of mezlocillin ($C_{21}H_{25}N_5O_8S_2$) in each mg of the Mezlocillin Sodium taken by the formula:

$$200(C / W)(r_U / r_S)$$

in which *C* is the concentration, in µg per mL, of mezlocillin ($C_{21}H_{25}N_5O_8S_2$) in the *Standard preparation*, *W* is the weight, in mg, of the portion of Mezlocillin Sodium taken to prepare the *Assay preparation*, and r_U and r_S are the mezlocillin peak responses obtained from the *Assay preparation* and the *Standard preparation*, respectively.

Mezlocillin for Injection

» Mezlocillin for Injection contains an amount of Mezlocillin Sodium equivalent to not less than 90.0 percent and not more than 115.0 percent of the labeled amount of mezlocillin ($C_{21}H_{25}N_5O_8S_2$).

Packaging and storage—Preserve in *Containers for Sterile Solids* as described under *Injections* ⟨1⟩.

USP Reference standards ⟨11⟩**—**
USP Endotoxin RS
USP Mezlocillin Sodium RS

Constituted solution—At the time of use, it meets the requirements for *Constituted Solutions* under *Injections* ⟨1⟩.

Bacterial endotoxins ⟨85⟩—It contains not more than 0.06 USP Endotoxin Unit per mg of mezlocillin.

Sterility ⟨71⟩—It meets the requirements when tested as directed for *Membrane Filtration* under *Test for Sterility of the Product to be Examined*.

Particulate matter ⟨788⟩: meets the requirements for small-volume injections.

Other requirements—It responds to the *Identification* tests and meets the requirements for *Specific rotation*, *pH*, and *Water* under *Mezlocillin Sodium*. It meets also the requirements for *Uniformity of Dosage Units* ⟨905⟩ and *Labeling* under *Injections* ⟨1⟩.

Assay—

Mobile phase, *Standard preparation*, *Resolution solution*, and *Chromatographic system*—Prepare as directed for the *Assay* under *Mezlocillin Sodium*.

Assay preparation 1 (where it is represented as being in a single-dose container)—Constitute Mezlocillin for Injection in a volume of water, accurately measured, corresponding to the volume of solvent specified in the labeling. Withdraw all of the withdrawable contents, using a suitable hypodermic needle and syringe, and dilute quantitatively with water to obtain a solution containing about 0.5 mg of mezlocillin per mL.

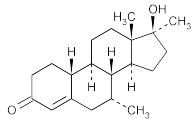
Assay preparation 2 (where the label states the quantity of mezlocillin in a given volume of constituted solution)—Constitute Mezlocillin for Injection in a volume of water, accurately measured, corresponding to the volume of solvent specified in the labeling. Dilute an accurately measured portion of the constituted solution quantitatively with water to obtain a solution containing about 0.5 mg of mezlocillin per mL.

Procedure—[NOTE—Use peak areas where peak responses are indicated.] Separately inject equal volumes (about 20 µL) of the *Standard preparation* and *Assay preparation 1* into the chromatograph, record the chromatograms, and measure the responses for the major peaks. Calculate the quantity, in mg, of mezlocillin in the container, or in the portion of constituted solution taken by the formula:

$$(L / D)(C / 1000)(r_U / r_S)$$

in which L is the labeled quantity, in mg, of mezlocillin in the container, or in the volume of constituted solution taken, D is the concentration, in mg per mL, of mezlocillin in *Assay preparation 1* or in *Assay preparation 2*, on the basis of the labeled quantity in the container, or in the portion of constituted solution taken, respectively, and the extent of dilution, C is the concentration, in µg per mL, of mezlocillin ($C_{21}H_{25}N_5O_8S_2$) in the *Standard preparation*, and r_U and r_S are the mezlocillin peak responses obtained from the *Standard preparation* and from *Assay preparation 1* or *Assay preparation 2*, as appropriate.

Mibolerone



$C_{20}H_{30}O_2$ 302.46

Estr-4-en-3-one, 17-hydroxy-7,17-dimethyl-, (7α,17β)-.

17β-Hydroxy-7α,17-dimethylestr-4-en-3-one [3704-09-4].

» Mibolerone contains not less than 96.0 percent and not more than 106.0 percent of $C_{20}H_{30}O_2$, calculated on the dried basis.

Packaging and storage—Preserve in well-closed containers.

Labeling—Label it to indicate that it is for veterinary use only.

USP Reference standards ⟨11⟩—

USP Mibolerone RS

Identification, *Infrared Absorption* ⟨197M⟩.

Specific rotation ⟨781S⟩: between +34° and +40°.

Test solution: 10 mg per mL, in chloroform.

Loss on drying ⟨731⟩—Dry about 1 g, accurately weighed, in a capillary-stoppered bottle in vacuum at a pressure not exceeding 5 mm of mercury at 60° for 3 hours: it loses not more than 0.5% of its weight.

Residue on ignition ⟨281⟩: not more than 0.5%.

Assay—

Mobile phase—Prepare a filtered and degassed mixture of water, tetrahydrofuran, and methanol (60:25:15). Make adjustments if necessary (see *System Suitability* under *Chromatography* ⟨621⟩).

Internal standard solution—Prepare a solution of progesterone in methanol containing 0.6 mg per mL.

Standard preparation—Prepare a solution of USP Mibolerone RS in *Internal standard solution* having a known concentration of about 0.4 mg per mL. Mix, and sonicate if necessary to achieve complete solution.

Assay preparation—Transfer about 10 mg of Mibolerone, accurately weighed, to a 25-mL volumetric flask, dilute with *Internal standard solution* to volume, and mix. Sonicate if necessary to achieve complete solution.

Chromatographic system (see *Chromatography* ⟨621⟩)—The liquid chromatograph is equipped with a 254-nm detector and a 3.9-mm × 30-cm column that contains packing L1. The flow rate is about 2 mL per minute. Chromatograph the *Standard preparation*, and record the peak responses as directed for *Procedure:* the relative retention times are about 0.6 for mibolerone and 1.0 for progesterone; and the relative standard deviation for replicate injections is not more than 2.0%.

Procedure—Separately inject equal volumes (about 5 µL) of the *Standard preparation* and the *Assay preparation* into the chromatograph, record the chromatograms, and measure the responses for the major peaks. Calculate the quantity, in mg, of $C_{20}H_{30}O_2$ in the portion of Mibolerone taken by the formula:

$$25C(R_U / R_S)$$

in which C is the concentration, in mg per mL, of USP Mibolerone RS in the *Standard preparation;* and R_U and R_S are the ratios of the peak responses of the mibolerone peak and the progesterone peak obtained from the *Assay preparation* and the *Standard preparation*, respectively.

Mibolerone Oral Solution

» Mibolerone Oral Solution contains not less than 90.0 percent and not more than 115.0 percent of the labeled amount of mibolerone ($C_{20}H_{30}O_2$).

Packaging and storage—Preserve in tight containers, protected from light.

Labeling—Label it to indicate that it is for veterinary use only.

USP Reference standards ⟨11⟩—

USP Mibolerone RS

Identification—The chromatogram of the *Assay preparation* exhibits a major peak for mibolerone, the retention time of which corresponds to that in the chromatogram of the *Standard preparation*, as obtained in the *Assay*.